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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/966,562	09/26/2001	F. Michael Shofner II	SEA-6-7-US-C	4670

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EXAMINER	
DAWSON, GLENN K	

ART UNIT	PAPER NUMBER
3761	10

DATE MAILED: 03/31/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/966,562	SHOFNER ET AL.	
	Examiner	Art Unit	
	Glenn K Dawson	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *10 and 11* is/are allowed.

6)☒ Claim(s) *1-8,12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,3-9,12 and 18-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Gerde-'512.

Gerde discloses several embodiments of powder inhalers wherein a metering chamber 12 receives an amount of powder, a jet 18 of gas fluidizes the powder and a mixing chamber 22(or portion thereabove) for allowing the aerosol generated to expand into a bolus for breathing by a patient.

Claims 1 and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Century-5570686.

Century discloses a metering chamber 114 which is filled with powder, and fluidized by a gas jet produced by either a syringe, pulsatile air source, or compressed gas container. The bolus produced enters a chamber downstream of valve 21 and thereafter exits tube 122 to the patient.

Claims 1,5,8,18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Minnesota Mining-EP 0 826 386 A2.

Minnesota Mining discloses a powder inhaler having a metering chamber 32, a gas jet 23 and a mixing chamber 16 and outlet 18.

Claims 1,4-6,8 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Barrington, et al.-4184258.

Barrington discloses a device having a metering chamber 24 filed with powder, a gas jet 28-30 for fluidizing the powder and a mixing chamber 25 and outlet 26.

Claims 13-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Blaha-Schnabel-5596982.

Blaha-Schnabel discloses a device which aerosolizes a solution of drug and solvent with a gas jet and allows it to expand into a bolus which is caused to dry to form a solute residue (powder). See col. 1 lines 20-37; col. 3 lines 5-20.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Century-'686 or Minnesota Mining-'386.

Century and Minnesota Mining disclose the invention as claimed with the exception of the specific size of the metering chamber. Century discloses that it was known to vary the size of the chamber... Minnesota Mining discloses a chamber having a volume of .24 mm^3.

It would have been obvious to have provided the chambers of Century or Minnesota Mining within the claimed parameters as merely an obvious design choice given that it was known to deliver extremely small quantities of powder to patients depending on the particular ailment and size or age of the patient. See In re Rose , 220 F.2d 459, 105 USPQ 237 (CCPA 1955).

Allowable Subject Matter

Claims 10 and 11 are allowed.

Response to Arguments

Applicant's arguments filed 12-19-03 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a different type of expansive bolus and mixing chamber) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

No explicit definition of the expansive bolus and the chamber were provided in the original specification, and therefore, the terms, given their broadest reasonable interpretation, are readable on by the applied prior art references. Each of the references discloses a bolus which expands at some point. Each of the references discloses a chamber (area) where the aerosol enters after formation.

Applicants also seek to define the present claims over the prior art by stating that the present invention does not use or have various elements or functions of the prior art references. For anticipation, elements or functions in excess of those claimed are irrelevant to the determination of anticipation, lacking the use of "consisting" in the preambles of the claims.

Any pocket is a metering pocket, as it holds a specific amount of powder. If one so desired, one could regulate the amount of product in the aerosol by filling the pocket.

Also, the amount of powder placed in the chamber has been metered by being a sealed cup or through the use of a dowel cup.

The recitations of the gas jet being continuous or impulsed are functional or intended use limitations. The prior art devices are capable of performing in either mode, if one so desired. There is also no recitation as to the amount of time the pulse of gas needs to be continuously delivered.

Gerde discloses in col. 9 lines 12-18 a mega dose disc in the form of a cartridge.

The predictable average mass flow rate is again entirely functional in nature. One could clearly predict the flow rate of the generator if one were to measure it at some point. The intended use noted in the preamble does not overcome the prior art. The limitation found in claim 17 is merely inherent. The flow of gas in the references is upward, and therefore, any particle whose settling velocity is higher than the upward flow velocity will fall out.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Glenn K Dawson whose telephone number is 703-308-4304. The examiner can normally be reached on M-Th 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Glenn K Dawson
Primary Examiner
Art Unit 3761

Gkd
03 February 2004